REMARKS

Applicants respectfully request reconsideration of the present Application. Claims 32, 41, and 49 have been amended herein without introducing any new matter. Claims 32-52 are currently pending and believed to be in condition for allowance in light of the above amendments and the following remarks.

Rejections based on 35 U.S.C. § 101

Claims 32-52 were rejected under 35 U.S.C. § 101 for allegedly being directed toward non-statutory subject matter. Independent claims 32 and 49 have been amended above to recite methods that are "implemented by a server," and thus are "tied to a particular machine" according to the Federal Circuit's decision in *In re Bilski*, 545 F.3d 943, 961 (Fed. Cir. 2008). Also, independent claim 41 has been amended to recite a system with a "server configured to execute" different modules, and therefore recites more than computer programs. Dependent claims 33-40, 42-48, and 51-52 inherit the features of these three independent claims and likewise recite statutory subject matter under § 101. Accordingly, Applicants request withdrawal of the § 101 rejection of claims 49-52.

Rejections based on 35 U.S.C. § 112

Claims 32-52 were rejected under 35 U.S.C. 112, second paragraph, for allegedly being indefinite. Specifically, the Office Action stated that the metes and bounds of the phrase "apply genetics to the at least one of clinical agent or the clinical event" in independent claims 32, 41, and 49 was indefinite because "[i]t is unclear how genetics is applied to a clinical agent which is not genetic in nature." *Office Action*, p. 5 (mailed July 16, 2009). Claim 49, however, does not recite the aforesaid claim feature, and in fact, does not mention a "clinical agent" at all. Therefore, the § 112 rejection of claim 49 and its progeny is improper under the Office Action's

rationale and should be withdrawn. Moreover, claims 32 and 41, as amended above, recite the language suggested in the Office Action, namely to use genetic techniques to characterize the person's response to an order for medication or a clinical agent. *See id.* The Office Action hinted that such language would overcome the § 112 rejection of claims 32, 41, and their progeny.

Rejections based on 35 U.S.C. § 103(a)

The basic requirements of a *prima face* case of obviousness are summarized in MPEP §§ 2143-2143.03. In particular, "the prior art reference (or references when combined) must teach or suggest all the claim limitations" in order to establish a *prima facie* case of obviousness. MPEP § 2143 (quoting *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). "If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." MPEP § 2143.03 (citing *In re Fine*, 837 F,2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)).

Claims 32-52 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,112,182 to Akers et al. ("Akers"), W.O. 2001/01218 to Denton et al. ("Denton"), and Pathak et al., *Automatic Computation of Genetic Risk*, 1043-0989/94, IEEE, 1994 ("Pathak"). In light of the amendments herein, the cited references do not obviate claims 32-52 for at least the following reasons.

Independent claim 32 is directed to a computer-implemented method for determining and presenting the likelihood a person has a mutated form of a gene. As amended herein, the method comprises "receiving an electronic order from a clinician for at least one of a clinical agent or a clinical event for a person, wherein the electronic order **does not indicate a request to use genetic techniques to characterize the person's response to the at** least one

clinical agent for the person." The method further recites "**in response to the electronic order**, querying a first database to determine if the person has one or more genetic test results for the gene; [and] **in response to the electronic order**, obtaining the mode of inheritance for the gene." Also, claim 32 recites "**without solicitation from a clinician**, querying a second database to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene."

The cited references fail to teach or suggest the aforesaid features. At best, Akers mentions a doctor selecting "a drug (identified by a NDC code)," (*Akers*, col.4 l.37-40), and Denton refers to mutations in genes may affect an individual (*See Denton*, p.3). Pathak, at most, discloses a system that receives a request for a risk assessment about a patient's genetics, calculates the risk, and outputs the risk assessment accordingly. *See Pathak*, FIG. 1 and p. 164. Yet, the cited references are silent about receiving an electronic order without a request to apply genetics and, based on the order, querying databases for genetic results to determine the likelihood a patient has a mutated gene. Therefore, the cited references do not teach or suggest each and every element of claim independent claim 32, as amended herein. Accordingly, Applicants respectfully request withdrawal of the § 103(a) rejection.

Independent claim 41 is directed to a computer system for determining and presenting the likelihood a person has a mutated form of a gene. The computer system comprises a receiving module, determining module, first querying module, obtaining module, second querying module, utilizing module, and presenting module. As amended herein, the receiving module is configured "for receiving an electronic order for at least one of a clinical agent for a person from a clinician, wherein the electronic order **does not indicate a request to use genetic techniques to characterize the person's response to the at least one clinical**

agent for the person." The determining module, as amended herein, is configured "for determining, **in response to receiving the electronic order**, whether the least one of clinical agent is associated with a gene." Similarly, the first querying module is configured "for querying, **in response to the electronic order**, a first database to determine if the person has one or more genetic test results for the gene if the at least one the clinical agent is associated with one or more genetic test results." The obtaining module is configured "for obtaining, **in response to the electronic order**, the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene." Finally, the presentation module is configured "for presenting the calculated likelihood the person has a mutated form of the gene to the clinician **without solicitation from the clinician for the calculated likelihood**."

As previously stated, none of the cited references describe receiving an electronic order that does not indicate a request to apply genetic and, based on the electronic order, determining the likelihood a user has a gene mutation. Nor do the references describe modules capable of performing such a task. Therefore, Applicants respectfully request withdrawal of the § 103(a) rejection.

As amended above, independent claim 49 recites "automatically calculating an inferred finding that the patient has a mutated form of the gene . . . based on a **Quantitative Trait Loci (QTL) analysis** of the one or more genetic findings associated with the one or more family members." The Specification supports this feature in ¶ 0062, describing the following embodiment:

> In this embodiment, the inferred results are calculated by utilizing genetic findings for linked genes or markers for the patient, genetic findings for linked genes or markers for one or more family members, and the genetic findings for one or more family members. Linkage analysis may be performed using

> **Quantitative Trait Loci (QTL) analysis** or any other approach known to those skilled in the art.

(emphasis added). Applicants respectfully submit that Akers, Denton, and Pathak do not teach or suggest the same way of calculating an inferred finding that a patient has a mutated form of a gene. Claim 49 is therefore not obvious in view of these cited references, and § 103(a) rejection should be withdrawn.

Additionally, dependent claims 33-40, 42-48, 50, and 51 are also in condition for allowance based, at least in part, on their dependence from one of independent claims 32, 41, and 49. Accordingly, Applicants respectfully request withdrawal of the § 102(b) rejections thereto.

CONCLUSION

For at least the reasons stated above, claims 32-52 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned at 816-474-6550 or phoeller@shb.com (such communication via email is herein expressly granted). If any additional fee is due for filing this response, the Commissioner is hereby authorized to charge any the additional amount required to Deposit Account No. 19-2112.

Respectfully submitted,

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